Certificate US19/819943430

The quality management system of

Kirwan Surgical Products LLC

180 Enterprise Drive, Marshfield, MA 02050, United States Of America

Facility number: F004229

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System
Brazil: RDC ANVISA n. 665/2022 - Good Manufacturing Practices; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009 - Vigilance
Canada: Medical Device Regulations SOR/98-282, Part 1
Japan: MHLW Ministerial Ordinance No.169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
Japan PMD Act (as applicable)
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities

Design and Development, Production and Distribution of Sterile and Non-Sterile Electrosurgical Handpieces, Bipolar Coagulators and Handpieces with Cords for the areas of surgery.

This certificate is valid from Effective date 2024-03-30 until Expiry date 2027-03-30 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2019-10-16

L. Henderson

Authorised by
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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.